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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO.
09/750,357	12/29/2000	Katsuhiko Tomita	Q62299	6888

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EXAMINER	
BROWN, JENNINE M	

ART UNIT	PAPER NUMBER
1755	

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No.	Applicant(s)	
	09/750,357	TOMITA, KATSUHIKO	
	Examiner	Art Unit	
	Jennine M. Brown	1755	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s) _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other

Finality

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Objections

Claim 1 is objected to because of the following informalities: "a molecular recognition layer formed on a sensor face of a chemical CCD, said molecules recognition layer selectively capture molecular of certain chemical substances." should read "a molecular recognition layer formed on a sensor face of a chemical CCD, said molecular recognition layer selectively capture molecules of certain chemical substances."

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Sawada, et al. (US 6255678 B1).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it

constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Sawada, et al. teach a chemical CCD having a plurality of potential wells, arranged two dimensionally, in which electric charges are injected into the potential wells and the chemical quantity is converted into an electric charge corresponding to the sizes of the potential wells; a molecular recognition layer formed on a sensor face of a chemical CCD, selectively captures molecules of a certain chemical substance (col. 2, l. 9-13; col. 4, l. 7-17, 34-65; col. 5, l. 7-40; col. 6, l. 47-53; col. 8, l. 22-41; col. 8, l. 66 – col. 9, l. 48).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafeman, et al. (US 5164319) in view of Marks, et al. (US 6203758).

Hafeman, et al. teach a chemical based CCD detector which uses AC, DC or pH as the sensing means as well as p and n doped electrodes in individual wells for using a molecular recognition layer for biochemical detection where charge is proportional to the quantity of a detected chemical (Figure 1; col. 2, l. 26-51; col. 3, l. 9-29, 40-58, 63-66; col. 4, l. 10-68; col. 5, l. 1-17; col. 6, l. 26 – col. 7, l. 8; col. 7, l. 38-68; col. 9, l. 51-59; col. 10, l. 6-34, 47-58; col. 10, l. 62 – col. 11, l. 32; col. 15, l. 25-32, 53-61; col. 16, l. 45-48; col. 18, l. 66 – col. 20, l. 16).

Hafeman, et al. do not specifically teach the molecular recognition layer over the sensor which uses molecular imprinting techniques for DNA in the polymer. Marks, et al. teach a molecular recognition layer over the sensor using molecular imprinting techniques for DNA where the imprinted polymer is used instead of a lipid bilayer or monolayer which was previously disclosed by Hafeman, et al. (col. 2, l. 39-44; col. 3, l. 38-40; col. 4, l. 43-65; col. 8, l. 25-50; col. 19, l. 11-25; col. 22, l. 49-54; col. 25, l. 30-32, 35; col. 26, l. 1-64).

It would have been obvious to one of ordinary skill in the art to modify the apparatus of Hafeman, et al. to use the molecularly imprinted polymer of Marks, et al. because the templated polymer material would be specific to the templated DNA

therefore a more accurate response to an unknown sample could be measured. This would decrease the amount of sample necessary to be used for the apparatus and increase the efficiency of the response of the apparatus as well.

Response to Arguments

Examiner cited the reference by Sawada, et al. due to the common inventorship and assignee with the instant application and disclosure of such common inventorship is also required by Applicants by the MPEP. The citation based on Sawada and argumentation based on Sawada, et al. refer solely to the reference cited. The arguments relating to Hafeman, et al. refer solely to Hafeman, et al. therefore they cannot be inconsistent. The references are both based on anticipation and have not been combined in any form in the rejection or argumentation and were mistakenly misread as such. The previous argumentation still stands.

Furthermore, pending argumentation in the Response of 12/10/2003, the examiner has fully considered the arguments prepared therein but they are not persuasive.

According to Sawada, et al., which is considered prior art to the instant application and commonly owned by Applicants, Figure 6 shows a cell (24) for accommodating a sample (23) where substrate (22) bounds cell at bottom and an electrode (25) brings the potential of the sample to a specified high level with respect to the substrate and applying a voltage across substrate causes the sensing section (6) to be in the depleted condition (causes "wells" and "barriers"). Figure 7 is an

enlargement of Figure 6 where the sensor sections (13) on the substrate (22) are used to convert the pH to electric charges which go to the output section (14) for converting the transferred electric charges into output signals. The electric charge section (8) comprises horizontal CCD (8H) and vertical CCD (8V). The molecular recognition layer disclosed was taught in column 8, lines 46-49, "In order to provide pH sensitivity an water resisting property, the nitride film 48 is deposited to about 800 A using CVD (see Fig. 16 (C))." The selectivity against water and $[H^+]$ concentration is a molecular recognition layer. Furthermore, "According to the pH two-dimensional distribution measuring equipment of the above-configuration, the pH at a plurality of positions of different solutions can be simultaneously measured. Since the pH simultaneously measured is converted to electric charges, the two-dimensional distribution of electric charges using the techniques such as CCD." (col. 8, l. 66 – col. 9, l. 5) The reference teaches that the chemical modification of the surface of the sensing section with a suitable sensitive material can measure ion concentration other than pH such as samples in varied fields such as electrochemical, chemical, environmental bioremediation, food microorganisms, ecological tissues and corrosion (col. 9, l. 6-48). "The embodiment can be applied to chemical sensing which selectively reacts by the specific sensitive layer of the sensor section as well as to any phenomena in which electric particles fluctuate at the interface by physical contact." (col. 9, l. 38-42) Therefore in applicants own words, as shown above, the reference teaches a chemical molecular recognition layer over the CCD.

Similarly, the mechanism employed by Hafeman, et al. is that there is a measurement of surface potential between at the interface of the insulative layer and the medium which is related to the presence and amount of analyte in the assay medium (col. 3, l. 40-58). The region of applied DC potential employed for the measurement is neither forward nor reverse biased because it is found that the rate of change in the DC applied potential is largest, when the circuit is operated at or near the flat band potential of the semiconductor provided the surface potential at the first (semiconductor electrode) and the second (counter electrode) change differently as a result of change in the composition or concentration of analyte (col. 9, l. 26-33) thus reacting as a chemical CCD. The assay medium can be a polymerized gel, lipid bilayer, polystyrenes, polyacrylamides, polyacrylates, polyolefins (col. 6, l. 62 – col. 7, l. 8) complexes of binding pair members with unbound species are also contemplated using antibody antigen, enzymes, conjugate binding pairs, sugars, haptens, receptors, ligand receptor pairs (col. 10, l. 47 – col. 11, l. 22). The chemical layer used to discriminate for the chemical to be determined which injects electrical signal and changes the surface potential of the semiconductor makes it a chemical CCD. Marks was combined to specifically teach DNA added to the polymer and that the polymer may be molecularly imprinted which was not specifically suggested by Hafeman, et al. but would be one of the available techniques since they are known in the art and are used on similarly made substrates. The CCD device responds by changing the depth of the potential wells by conversion of the amount of chemical adhering to the polymeric layer

to charge and are then interpreted to be the amount of the specific chemical one is trying to determine. The argumentation about sensitivity is moot because it is not claimed in claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennine M. Brown whose telephone number is (571) 272-1364. The examiner can normally be reached on M-F 8:00 AM - 6:00 PM; first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell can be reached on (571) 272-1362. The fax phone number for the examiner where this application or proceeding is assigned is (571) 273-1364.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1200.

jmb

ELIZABETH D. WOOD
PRIMARY EXAMINER
AU 1755

11/12/04